

## **Draft Guidance on Prednisone**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

**Active Ingredient:** Prednisone

**Dosage Form; Route:** Tablet; oral

### **Recommended Studies:**

Prednisone Tablet is a Drug Efficacy Study Implementation (DESI) effective drug product without known bioequivalence problems. Therefore, in vivo bioequivalence testing is not recommended. The waiver of in vivo bioequivalence study requirements on this product may be requested under 21 CFR 320.22(c). Comparative dissolution testing on 12 dosage units of all strengths of the test and reference products shall be conducted to demonstrate the bioequivalence.

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**Analytes to measure (in appropriate biological fluid):** Not applicable

**Bioequivalence based on (90% CI):** Not applicable

**Waiver request of in vivo testing:** 1 mg, 2.5 mg, 5 mg, 10 mg, 20 mg, 50 mg pursuant to 21 CFR 320.22(c).

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).

All strengths of prednisone tablets are scored. For additional information on the evaluation of scored tablets, refer to the FDA Guidance on "Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation" issued in March 2013 at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269921.pdf>.